INCITE
INNOVATION

MAR 2 4 2010

510k Summary

As required by section 807.92(c)

Company Name	Incite Innovation LLC
Address	1350 Main Street Springfield, MA 01103 413-382-0210 Phone 413-382-0211 Fax
Contact Person	John Kirwan
Date	March 1, 2010
Trade Name	Incite Interbody Fusion Device
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral body fusion device, 21 CFR Part 888.3080, MAX
Class	II, Special Controls
Predicate Devices	LDR ROI – A™ ALIF Cage with Vertebridge™ Technology and LDR ROI-T TLIF Cage (K082262) Synthes Synfix™-LR System (K072253) Biomet Solitaire™ PEEK-Optima® Anterior Spinal System (K081395) Spine-Tech BAK™ Interbody Fusion System (P950002)
Device Description	The Incite Interbody Fusion Device (IBFD) is an ALIF implant that incorporates the benefit of a radiolucent interbody spacer equipped with internal fixation anteriorly through the use of an integrated anchoring mechanism. The implant is made from materials with a long history of use in this type of application which include PEEK, titanium alloy, and tantalum. The implant has two chambers to accommodate autograft.
Intended Use	The Incite Interbody Fusion Device is intended for anterior intervertebral body fusion of the lumbar spine at one or two contiguous levels from L2-S1. The device is indicated for patients with lumbar degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients treated should be skeletally mature and have received a minimum of six months of non-operative treatment. The Incite Interbody Fusion Device is designed for use with additional supplemental fixation and with autograft to facilitate fusion.
Substantial Equivalence	The intended use, device design, materials, and mechanical performance data demonstrate that the proposed Incite Interbody Fusion Device is substantially equivalent to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 12 2011

Incite Innovation, LLC
% Mr. John Kirwan
1350 Main Street, Suite 1506
Springfield, Massachusetts 01103

Re: K093808
Trade/Device Name: Incite Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: March 1, 2010
Received: March 2, 2010

Dear Mr. Kirwan:

This letter corrects our substantially equivalent letter of March 24, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K093808

Device Name: Incite Interbody Fusion Device

Indications for Use:

The Incite Interbody Fusion Device is intended for anterior intervertebral body fusion of the lumbar spine at one or two contiguous levels from L2-S1. The device is indicated for patients with lumbar degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients treated should be skeletally mature and have received a minimum of six months of non-operative treatment. The Incite Interbody Fusion Device is designed for use with additional supplemental fixation and with autograft to facilitate fusion.

Prescription Use ___X___ AND/OR Over-The_Counter Use_____

(PLEASE DO NOTR WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093808

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